Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The Comparison between effect of high intensity and low intensity laser therapy on pain, disability and joint effusion in patients with chronic knee osteoarthritis grade 1,2: A Randomized Clinical Trial

Protocol summary

Study aim
The Comparison between effect of high intensity and low intensity laser therapy on pain, disability and joint effusion in patients with chronic knee osteoarthritis grade 1,2

Design
A randomized, controlled, blinded, clinical trial with a parallel group design of 71 patients

Settings and conduct
The effects of laser therapy in patients with osteoarthritis. All procedures will be performed in khatam hispital, zahedan university of medical sciences. The patients will be in 3 groups double blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 40-60 yrs; Osteoarthritis grade 1 or 2. non-iclusion criteria: Rheumatoid arthritis; complete tear anterior cruciate ligament or menisci; Hyalgan or corticosteroids injection in last 6 months; Grade 3 and 4 osteoarthritis

Intervention groups
1-Control group: 1) The Infrared bulb is positioned at a distance of 50 cm from the knee. 2- Transcutaneous electrical nerve stimulation(TENS) 3- Exercise for strengthening,stretching,rane of motion muscle should include 6 exercises . 2- Low level laser therapy Treatments in control group and low level laser therapy 3- High power laser therapy Treatments in control group and high power laser therapy

Main outcome variables
Supra patella effusion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516034003N8**
Registration date: **2019-09-15, 1398/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**
Update count: **0**

Registration date
2019-09-15, 1398/06/24

Registrant information

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Kamran Ezzati

Name of organization / entity
Guilan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-08, 1398/04/17

Expected recruitment end date
2019-10-09, 1398/07/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Comparison between effect of high intensity and low intensity laser therapy on pain, disability and joint effusion in patients with chronic knee osteoarthritis

grade 1,2: A Randomized Clinical Trial

Public title
The effects of laser therapy on symptoms of patients with knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Radiologic signs of grade 1 and 2 Kellgren-Lawrence: Decrease of joint space and existence of osteophytes Body mass index<40
Exclusion criteria:
The patients with rheumatoid arthritis; malignancy; knee surgery; fracture; complete tear anterior cruciate ligament or menisci; athletics; neuropathy, hyalgan or corticosteroids injection in last 6 months.Physiotherapy in last month Grade 3 and 4 Kellgren-Lawrence in radiologic examination Local infection Referral pain from lumbar or hip to knee
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **71**
More than 1 sample in each individual
Number of samples in each individual: **2**
One participant may have osteoarthritis in Both knees, and both knees are used in this study as sample.
Randomization (investigator's opinion)
Randomized
Randomization description
The grouping method will be stratified permuted block randomization . Equal number of patients from 3 groups will be matched based on age, Body mass index. So, 3 blocks of 10 people for 3 groups will be allocated. A software engineer at the ward will perform this method
Blinding (investigator's opinion)
Single blinded
Blinding description
Although routine physical therapy will be performed for all patients, they won`t know anything about laser therapy and the kind of it. So, the patients are blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of zahedan University of Medical Sciences
Street address
daneshgah blvd, dr hessabi square
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2019-07-07, 1398/04/16
Ethics committee reference number
IR.ZAUMS.REC.1398.140

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
M17.1
ICD-10 code description
Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description
Pain
Timepoint
Before intervention, After ten sessions treatments, one month follow-up
Method of measurement
Visual Analogue Scale

2

Description
Area of supra patella effusion
Timepoint
Before intervention, After ten sessions treatments, one month follow-up
Method of measurement
Using ultrasonography

3

Description
Thickness of supra patella effusion
Timepoint
Before intervention, After ten sessions treatments, one month follow-up
Method of measurement
Using ultrasonography

4

Description
Disability
Timepoint
Before intervention, After ten sessions treatments, one month follow-up
Method of measurement
WOMAC questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 1-Control group: Interventions in this group include: 1) Infrared therapy for 20 minutes: The Infrared bulb is positioned at a distance of 50 cm from the knee of the individuals. The patient will feel mild heat. 2- Treatment with transcutaneous electrical nerve stimulation(TENS) type brief for 20 minutes. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations about 20 minutes. 3- Exercise for strengthening,range of motion, stretching muscle should include 6 exercises.
Category
Rehabilitation

2

Description
Int Low level laser therapy: All interventions in control group with low level laser therapy: Laser therapy (laser med, Carci, brazil) with 905 nm wavelength, 12 joules, 50 mW on 10 points of the knee. Each point treatment time will be 912 seconds.
Category
Rehabilitation

3

Description
Intervention group: High power laser therapy: All interventions in control group with high power laser therapy: Laser therapy (High power laser,New Age , Italy) with 905 nm wavelength, 12 joules, 1.6W on all areas of the . Treatment time will be 300 seconds.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam hospital
Full name of responsible person
Fatemeh Ghiasi
Street address
Physiotherapy section, khatam hospital,jaam jam boulevard, Zahedan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person

Anahita Hasannejad
Position
student
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Bachelor
Other areas of specialty/work
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Fax
Email
Ez_kamran@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Sharing is done after the end of the study. The total potential data can be shared after unidentifications of individuals.
When the data will become available and for how long
Start the access period 6 months after publicating the results
To whom data/document is available
Researchers working in universities
Under which criteria data/document could be used
Researchers working in universities
From where data/document is obtainable
Adress: Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht. Ez_kamran@yahoo.com
What processes are involved for a request to access data/document
A written request for data from the relevant university with the name and academic degree of the researche
Comments